510(k) Summary:

UNO Narrow Implant

JAN - 5 2010

Company Name: MIS Implants Technologies Ltd.
P.O.Box 7, Bar Lev Industrial Park,
20156, ISRAEL
Telephone: +972-4-9016800
Fax: +972-4-9918623

Establishment Registration Number: 3004203816

Contact Name: Iman Khorshid
V.P QA & RA
Telephone: +972-4-9016800
Fax: +972-4-9918623
E-mail: iman@mis-implants.com

US Agent: Motti Weisman - VP Marketing
MIS Implants Technologies Inc.
14-25 Plaza Rd. Suite S-3-5 Fair Lawn
New Jersey; 07410
Phone: (201) 797-9144
Fax: (201) 797-9145
E-mail: service@misimplants.com

Date prepared: August 12, 2009

Trade Name: UNO Narrow Implant

Classification name: Implants, Endosseous, Root Form

Common/usual name: Dental Implant

Product Code: DZE; NHA

Regulation No.: 872.3640; 872.3630

Class: II

Panel identification: Dental Devices Panel

Predicate Device:

OssseoSpeed ™ Narrow from Astra Tech AB , Aminogatan 1, P.O.Box 14, Mölndal, Sweden SE-431-21 cleared under 510(k) No. K080396.

Description of the device:

The UNO Narrow Implant is a self tapping, root-form, two piece screw type dental implant, indicated for use in surgical and restorative applications for placement in the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function.

The UNO Narrow Implant is provided in one diameter (3 mm) in the following lengths: 10mm, 11.5 mm, 13mm and 16mm. See Annex 1 of this section.

The implants are tapered with double thread (2mm pitch) for fast insertion.

The implants surface is sand blasted and acid etched .See Annex 2 of this section.

The UNO Narrow Implant is a two piece device whereas the implant is to be used in combination with replaceable ball attachments anchor screws and healing caps.

See implantation procedure in Annex 3 of this section.

The Uno implants and healing caps are supplied sterile and are intended for single use only.

The ball attachment anchor screws are supplied non-sterile since immediately after their placement the ball attachments are used for impression coping in plastic materials.

The UNO Narrow Implants are made of Ti6AL4V ELI complying with standard ASTM F 136-02- Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant.

Indications for Use:

The UNO Narrow Implant is indicated for use in surgical and restorative applications for placement in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws where the horizontal space is limited by adjacent teeth and roots, to provide support for prosthetic devices such as artificial teeth, in

order to restore the patient chewing function. Mandibular central and lateral incisors must be splinted if using two or more Ø3.0 mm implants adjacent to one another. The UNO Narrow Implant is indicated for immediate implantation in extraction sites or implantation in partially healed or completely healed alveolar ridge situations. When a one stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the functional load is appropriate.

Substantial Equivalence:

The UNO Narrow Implants have the same intended use as the **OsseoSpeed™ Narrow Implant from Astra Tech AB , Aminogatan 1, P.O.Box 14, Mölndal, Sweden SE-431-21 cleared under 510(k) No. K080396**, and have equivalent performance characteristics. Both products are manufactured from the same Titanium alloy. All other technological characteristics are similar except for the surface treatment and show equivalent performance capabilities. The UNO Narrow Implants are therefore substantially equivalent to the predicate device.

Conclusion:

The evaluation of the UNO Narrow Implants does not raise any additional concerns regarding safety and effectiveness and may therefore be considered substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JAN - 5 2010

Ms. Iman Korshid
Vice President
MIS Implants Technologies Limited
P.O.B. 110, Shlomi Industrial Zone
Shlomi 22832
ISRAEL

Re: K092555
Trade/Device Name: UNO Narrow Implant
Regulation Number: 21CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: December 17, 2009
Received: December 22, 2009

Dear Ms. Korshid:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, BS, MS, MBA
Director
Division of Anesthesiology, General Hospital,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K092555

Device Name: UNO Narrow Implant

Indications for Use: The UNO Narrow Implant is indicated for use in surgical and restorative applications for placement in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws where the horizontal space is limited by adjacent teeth and roots, to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function. Mandibular central and lateral incisors must be splinted if using two or more Ø3.0 mm implants adjacent to one another. The UNO Narrow Implant is indicated for immediate implantation in extraction sites or implantation in partially healed or completely healed alveolar ridge situations. When a one stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the functional load is appropriate.

Prescription Use ___X___ OR Over the Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulloy for HSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092555